K103019

JUN - 9 2011

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 09/29/2010

1. Company making the submission

	Submitter
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Contact	Nam-goong San, Assistant Manager

2. U.S Agent/Contact Person

LK Consulting Group
2341 W. Crescent Ave. # 3, Anaheim, CA 92801
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3. Device

Trade Name: KJ Mask
Common Name: Orthodontic Face Mask
Classification Name: Extraoral Orthodontic Headgear
Classification regulation: 21CFR872.5500
Product Code: DZB

2. Predicate Device:

ADP Face Mask by Ormco Corp. (K923556)

3. Description:

KJ Mask (KM 102-S, KM 201-L) is a device made of materials such as aluminum alloy, stainless steel and plastic intended to be placed on face for the purpose of

orthodontics.

The device is constructed of four parts, a chip cup, forehead rest, cross bar and main frame. It is intended to exert orthopedic or orthodontic forces of the maxillary arch in order to effect a change in the position of the maxilla in relation to the mandible and other facial structures.

4. Indication for use:

KJ Mask is used as a treatment option for Class III malocclusions.

5. Basis for Substantial Equivalence

KJ Mask and the predicate device consist of almost the same components. The similarity in design between KJ Mask and the predicate device supports the safety and effectiveness of KJ mask for the indicated use.

KJ Mask is substantially equivalent to the predicate device in terms of indications, compositions, material, design, safety and effectiveness.

6. Conclusion

Based on the information provided in this premarket notification, KJ Meditech Co., Ltd. concludes that KJ Mask is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KJ Meditech Company, Limited
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street, Unit J
Fullerton, California 92833

JUN - 9 2011

Re: K103019
Trade/Device Name: KJ Mask
Regulation Number: 21 CFR 872.5500
Regulation Name: Extraoral Orthodontic Headgear
Regulatory Class: II
Product Code: DZB
Dated: May 31, 2011
Received: June 3, 2011

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103019

Device Name: KJ Mask

Indications For Use:

KJ Mask is used as a treatment option for Class III malocclusions.

Prescription Use __√__ **AND** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEE DED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103019